Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)

Completed Actions

763. CONTROL OF COMMUNICABLE DISEASES

Priority: Other Significant

CFR Citation: 42 CFR 70; 42 CFR 71

Completed:

Reason	Date
Interim Final Rule	04/10/03 68 FR 17558

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Jennifer Brooks
Phone: 404 639-2763

RIN: 0920–AA03

764. POSSESSION, USE, AND TRANSFER OF SELECT AGENTS

Priority: Other Significant

CFR Citation: 42 CFR 72; 42 CFR 72.6

Completed:

Reason	Date
Interim Final Rule	12/13/02 67 FR 76886

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Stephen M. Ostroff
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RIN: 0920–AA08

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

Prerule Stage

765. OVER-THE-COUNTER (OTC) DRUG REVIEW

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 350

Legal Deadline: None

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed.

SMALL ENTITIES AFFECTED: The effects, if any, vary depending on the individual rulemaking. However, the Agency anticipates that the rules would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

Timetable:

Anorectal Products
Final Action (Amendment) 12/00/03
Antidiarrheal Products
Final Action 04/17/03 (68 FR 18869)
NPRM (Amendment) (Trav.Diar) 04/17/03 (68 FR 18915)
Antiemetic Products
Final Action (Amendment) (Warning) 12/06/02 (67 FR 72555)
Antiperspirant Products
Final Action 08/00/03
Cough/Cold (Antihistamine) Products
Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)
Cough/Cold (Antitussive) Products
Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)
Cough/Cold (Bronchodilator) Products
Final Action (Amendment) 02/00/04
Cough/Cold (Combination) Products
Final Action 12/23/02 (67 FR 78158)
NPRM (Amendment) 02/00/04
Cough/Cold (Nasal Decongestant) Products
NPRM (Phenylpropanolamine) 10/00/03
External Analgesic Products
Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)
NPRM (Amendment) (Patches) 12/00/03
Ingrown Toenail Relief Products
NPRM 10/04/02 (67 FR 62218)
Final Action 06/00/03
Internal Analgesic Products
NPRM (Amendment) (Ibuprofen) 08/21/02 (67 FR 54139)
NPRM (Amendment) (Pediatric) 10/00/03
NPRM (Amendment) (Labeling) 12/00/03
Labeling of Drug Products for OTC Human Use
Final Action (Ca/Mg/K/Na) 07/00/03
Final Action (Sodium Labeling) 07/00/03
NPRM (Sodium Labeling) 07/00/03
NPRM (Convenience Sizes) 09/00/03
Laxative Drug Products
NPRM (Amendment) (Psyllium Granular Dosage Form) 10/00/03
Nighttime Sleep Aid Products
Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)
Ophthalmic Products
Final Action (Technical Amendment) 02/19/03 (68 FR 7919)
NPRM (Emergency First Aid Eyewashes) 02/19/03 (68 FR 7951)
Final Action (Name Change) 06/00/03
Oral Health Care Products
ANPRM (Plaque/Gingivitis) 06/00/03
Pediculicide Products
NPRM (Labeling Amendment) 05/10/02 (67 FR 31739)
Final Action (Labeling Amendment) 02/00/04
Salicylate (Reye's Syndrome)
Final Action (Warning) 04/17/03 (68 FR 18861)
Skin Protectant Products
Final Action 07/00/03
NPRM (Astringent) 09/00/03
Final Action (Astringent) 09/00/03
Sunscreen Products
Final Action (Names) 06/20/02 (67 FR 41821)
ANPRM (and Insect Repellent) 10/00/03
NPRM (UVA/UVB) 12/00/03
Vaginal Contraceptive Products
NPRM (Amendment) 01/16/03 (68 FR 2254)
Weight Control Products
NPRM (Phenylpropanolamine) 10/00/03

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AA01

766. INVESTIGATIONAL USE NEW ANIMAL DRUG REGULATIONS (SECTION 610 REVIEW)

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: 5 USC 610; 21 USC 351; 21 USC 353; 21 USC 360b; 21 USC 371; 21 USC 321; 21 USC 352

CFR Citation: 21 CFR 511

Legal Deadline: None